

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET
P.O. BOX 1347
WILMINGTON, DELAWARE 19899-1347

(302) 658-9200
(302) 658-3989 FAX

KAREN JACOBS LOUDEN

(302) 351-9227
(302) 425-4681 FAX
klouden@mnat.com

REDACTED -- Public Version
Original Filing Date: February 1, 2013
Redacted Filing Date: February 8, 2013

BY E-FILING AND FAX

The Honorable Joel Schneider
United States District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Room 1050
Camden, New Jersey 08101

Re: *Sciele Pharma, Inc., et al. v. Lupin Ltd., et al.*, C.A. No. 09-037-RBK-JS

Dear Magistrate Judge Schneider

Plaintiff Sciele Pharma, Inc., n/k/a Shionogi Inc. (“Shionogi”), and Plaintiffs Andrx Corporation; Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc. – Florida); Andrx Pharmaceuticals, L.L.C., Andrx Laboratories (NJ), Inc.; Andrx EU Ltd.; and Andrx Labs, L.L.C. (collectively, “Andrx” and collectively with Shionogi, “Plaintiffs”), seek leave to amend their infringement and validity contentions pursuant to Rule 3.7 of the New Jersey Local Patent Rules (“L. Pat. R.”) and the Court’s direction at the November 29, 2012 status conference. (11/29/2012 Hearing Tr. at 6:3-7). Plaintiffs seek to supplement their February 29, 2012 and March 20, 2012 infringement and validity contentions with the citations and statements already disclosed in their August 15, 2012 supplemental discovery responses. Based on the reasons set forth below, Plaintiffs respectfully request that the Court grant their motion.

I. Background of Plaintiffs’ Contentions

This action arises out Lupin Ltd. and Lupin Pharmaceuticals, Inc.’s (collectively, “Lupin”) and Mylan Inc. and Mylan Pharmaceuticals Inc.’s (collectively, “Mylan” and collectively with Lupin, “Defendants”) filing of Abbreviated New Drug Applications (“ANDA”) for generic copies of Shionogi’s Fortamet® metformin product, and Lupin’s subsequent at-risk

The Honorable Joel Schneider

February 1, 2013

Page 2

launch and infringing sales of generic Fortamet®. Plaintiffs brought this patent infringement suit alleging infringement of two patents – U.S. Patent Nos. 6,099,859 (the “859 patent”) and 6,866,866 (the “866 patent”). The relevant facts are:

- Plaintiffs served their initial Disclosure of Asserted Claims and Infringement Contentions upon Defendants on December 10, 2010, pursuant to the Court’s October 1, 2010 Scheduling Order (D.I. 56 at ¶ 1(f)). (*See* D.I. 71.)
- Plaintiffs served, as of right, supplemental infringement contentions (“Infringement Contentions”) on February 29, 2012 (D.I. 358), pursuant to this Court’s December 16, 2011 Amended Scheduling Order (D.I. 292 at ¶ 4).
- Plaintiffs responded to Defendants’ invalidity contentions (“Validity Contentions”) on March 20, 2012 (D.I. 379), pursuant to L. Pat. R. 3.4A.

On August 15, 2012, Plaintiffs served their second supplemental infringement contentions (“Supplemental Infringement Contentions”). (D.I. 538). As shown in Exhibits A and B, Plaintiffs did not add new claims or new theories of infringement, but simply provided additional factual support for their existing contentions that had come to light during the discovery process. On August 15, 2012, Plaintiffs also served supplemental validity contentions (“Supplemental Validity Contentions”) responding to statements made in Lupin’s June 12, 2012 and Mylan’s June 29, 2012 supplemental interrogatory responses and to the Federal Circuit’s July 2, 2012 decision in this case. (*See* D.I. 538.) During the November 29, 2012 status conference, the Court instructed the parties to seek leave to supplement their contentions. (11/29/2012 Hearing Tr. at 6:3-7). Accordingly, by this motion, Plaintiffs now seek leave to formally supplement their Infringement and Validity Contentions with the additional support included in their Supplemental Contentions served on August 15, 2012.

Based on the meet and confers between the parties held on January 18 and 31, 2013, there appears to be no dispute that under the Court’s December 16, 2011 Amended Scheduling Order and the Local Patent Rules, Plaintiffs were entitled to supplement their initial infringement contentions on February 29, 2012 and to respond to the Defendants’ invalidity contentions on March 20, 2012. Instead, Lupin argues that Plaintiffs’ August 15, 2012 Supplemental Contentions were served too late.¹ This objection rings hollow, however, because Lupin cannot show any prejudice resulting from Plaintiffs’ supplementation. The Supplemental Contentions do not introduce new theories or modify any of Plaintiffs’ original theories of infringement or validity. Rather, Plaintiffs only supplemented their February 29, 2012 Infringement and March 20, 2012 Validity Contentions to include additional facts which were not discovered or made relevant until after those dates.

¹ Mylan has not consented to the present motion and has not provided its basis for opposing.

The Honorable Joel Schneider

February 1, 2013

Page 3

For example, in Plaintiffs' Supplemental Infringement Contentions concerning Lupin, Plaintiffs added: (1) citations to six, publicly available scientific publications; (2) a two-sentence statement [REDACTED]

[REDACTED] See Ex. A, Supplemental Infringement Contentions to Lupin Redline at Ex. A. As to Mylan, Plaintiffs merely added a one sentence description of [REDACTED]

[REDACTED] See Ex. B, Supplemental Infringement Contentions to Mylan Redline at Ex. A.

For the Supplemental Validity Contentions, Plaintiffs added brief sections addressing newly-raised arguments in Defendants' respective supplemental interrogatory responses regarding the lack of patent misuse and no reasonable expectation of success. See Ex. C, Supplemental Validity Contentions to Lupin Redline at pp. 13-14, 17-18; Ex. D, Supplemental Validity Contentions to Mylan Redline at pp. 30-32. As to Lupin, Plaintiffs added a brief section regarding why the combination of two previously addressed references did not render the '866 patent obvious. See Ex. C, Supplemental Validity Contentions to Lupin Redline at pp. 12-13.

Illustrating the lack of prejudice, Lupin waited three months after Plaintiffs served their Supplemental Contentions to assert, for the first time, an objection solely based on the procedural argument that Plaintiffs did not first seek leave from this Court. (D.I. 568 at p. 10.) Lupin made no substantive arguments that Plaintiffs lacked good cause or that Lupin was prejudiced in any way. *Id.* At the November 29, 2012 status conference, (11/29/2012 Hearing Tr. at 6:3-7), this Court directed the parties to file motions to supplement contentions. Accordingly, Plaintiffs now move to supplement their February 29, 2012 and March 20, 2012 Contentions with the citations and statements included in the Supplemental Contentions, first served on August 15, 2012. Based on the reasons set forth below, Plaintiffs respectfully request this Court grant their motion.

II. Good Cause Exists for Plaintiffs' Request for Leave to Amend

Plaintiffs have good cause to amend their Infringement and Validity Contentions. There are four factors in determining whether good cause exists under L. Pat. R. 3.7: (1) the reason for the delay and whether the moving party has been diligent; (2) the availability of a continuance and potential impact of a delay on judicial proceedings; (3) the danger of unfair prejudice; and (4) the importance of what is being excluded. *Oy Ajat, Ltd. V. Vatech Am., Inc.*, No. 10-4875 (PGS), 2012 WL 1067900, at *20 (D.N.J. Mar. 29, 2012).

Good cause exists for Plaintiffs to amend their Infringement and Validity Contentions to incorporate evidence discovered as a result of Plaintiffs' timely investigation concerning infringement and validity, as well as to address new developments in the case. See *Arbitron, Inc. v. Int'l Demographics Inc.*, No. 2:06-CV-434 (TJW), 2008 WL 4755761, at *2 (E.D. Tex. Oct.

² Matrix is now called Mylan Laboratories Limited.

The Honorable Joel Schneider

February 1, 2013

Page 4

29, 2008).³ These additions to Plaintiffs' potentially dispositive claims and defenses will neither delay the proceedings nor prejudice Defendants.

A. Plaintiffs Have Shown Diligence in Developing Their Claims and Defenses

Plaintiffs diligently supplemented their validity contentions. As stated above, all of their amendments were made in direct response to either Defendants' supplemental interrogatory responses or statements made in a recent Federal Circuit opinion. On June 12, 2012, Lupin served a supplemental interrogatory response contending, for the first time, patent misuse concerning the '866 patent. *See* Ex. E, Lupin's Supplemental Responses to Interrogatory Nos. 11 and 12 at pp. 3-4. Mylan served a similar supplemental response shortly thereafter. Ex. F, Mylan's Supplemental Responses and Objections to Shionogi's First Set of Interrogatories to Mylan (Interrogatory Nos. 11-13) at pp. 6-9. Plaintiffs served their Supplemental Validity Contentions in August to respond to those newly-raised arguments. Similarly, Plaintiffs amended their obviousness arguments in direct response to the Federal Circuit's preliminary injunction opinion, which issued on July 2, 2012. *See Sciele Pharma Inc. v. Lupin Ltd*, 684 F.3d 1253 (Fed. Cir. 2012). Having supplemented their validity contentions approximately one month after the Federal Circuit's opinion, and two months after Defendants raised a new invalidity theory, Plaintiffs clearly were diligent in asserting their responsive contentions.

Approximately nine months before the submission of opening expert reports, Plaintiffs' supplemental infringement contentions identified [REDACTED]

³ The Court in *TFH Publ'ns., Inc. v. Doskocil Mfg. Co.*, 705 F. Supp. 2d 361 (D.N.J. April 5, 2010) noted the similarity between the local patent rules in the District of New Jersey, the Eastern District of Texas and the Northern District of California, and indicated that it was appropriate to consider precedent from all three districts for guidance. *Id.* at 366, n.3.

The Honorable Joel Schneider
February 1, 2013
Page 5

B. Supplementation At This Stage of the Litigation Will Not Delay the Proceedings

Plaintiffs' Supplemental Contentions will have no effect on the schedule in this case. Fact discovery closes at the end of February, and Defendants have known of Plaintiffs' proposed amendments for over five months. Indeed, Plaintiffs served their Supplemental Contentions over six months before the close of fact discovery; seven months before the submission of any expert report; and almost a year before the close of expert discovery. In fact, neither Lupin nor Mylan has contended that supplementation will impact other scheduled deadlines. Accordingly, Plaintiffs' Supplemental Contentions will have no effect on the current schedule in this matter.

C. Supplementation Will Not Prejudice the Defendants

Defendants cannot claim any prejudice by supplementation because Plaintiffs' Supplemental Infringement Contentions do not include any new or modified theories of infringement. Rather, the supplementations simply provide additional factual evidence supporting positions that were previously asserted and known to Lupin and Mylan for months. Indeed, Plaintiffs have always contended that [REDACTED]

See Ex. A, Supplemental Infringement Contentions concerning Lupin Redline at Ex. A, pp. 1-2; Ex. B, Supplemental Infringement Contentions concerning Mylan Redline at Ex. A, pp. 2-3. Because this supplementation does not materially or substantively change the nature of Plaintiffs' infringement positions, the amendments do not prejudice Defendants and should be allowed. See *Golden Hour Data Sys. Inc. v. Health Servs. Integration, Inc.*, No. 06-7477 SI, 2008 U.S. Dist. LEXIS 75495, at *13 (E.D. Tex. July 1, 2008) (finding no prejudice from supplementation when "amendments do not raise new issues but instead merely supplement [the] initial contentions").

Furthermore, courts consistently evaluate prejudice based on whether permitting the amendment would require the opposing party to invest "significant additional resources." See *TFH Publ'ns., Inc. v. Doskocil Mfg. Co.*, 705 F. Supp. 2d 361, 366 (D.N.J. April 5, 2010). That is of no concern here. Defendants will not have to invest additional resources evaluating the supplemental contentions, because Plaintiffs are not seeking to assert any new claims nor are Plaintiffs seeking to substantively modify their infringement or validity theories. Furthermore, at least some of the additional factual evidence is derived from Defendants' own documents produced in discovery in this matter, which should require minimal, additional analysis by the Defendants. *Id.* Nor will Defendants need to invest significant additional resources regarding validity because Plaintiffs are only seeking a minor amendment with respect to their Validity Contentions. Indeed, Plaintiffs are not putting forth any new validity theories. To the contrary, Plaintiffs have only added to their non-obviousness argument, leaving their contentions regarding anticipation, enablement, definiteness, written description, and secondary considerations unchanged. See Ex. C, Supplemental Validity Contentions to Lupin Redline; Ex. D, Supplemental Validity Contentions to Mylan Redline. Furthermore, Defendants have been on notice of Plaintiffs' proposed amendments since August 2012, over seven months before opening expert reports are due in April 2013.

The Honorable Joel Schneider

February 1, 2013

Page 6

Accordingly, Defendants' experts will have had ample opportunity to address Plaintiffs' infringement and validity contentions, in expert reports. *See Golden Hour Data Sys.*, 2008 U.S. Dist. LEXIS 75495, at *14 (finding no prejudice from supplementing contentions because "expert discovery ha[d] not yet begun, [and the opposing party's] experts will have the opportunity to consider the amended contentions.").

During a meet and confer between the parties, Lupin argued that it is prejudiced by the Supplemental Contentions because Plaintiffs are seeking supplementation after the claim construction proceedings. But, that argument is without merit. The Court issued its Claim Construction Order on September 15, 2011. (D.I. 191.) Yet, the December 16, 2011 Amended Scheduling Order permitted supplementation of contentions **as of right**, until February 29, 2012. (D.I. 292.) As the Court expressly permitted supplementation **after** claim construction, Lupin's argument fails for this reason alone.⁴ (*See* D.I. 144.) Indeed, Lupin itself filed supplemental contentions on February 29, 2012. (D.I. 359.) Lupin has not (and cannot) explain how any "delay" between service of Plaintiffs' contentions in February and March 2012, and their Supplemental Contentions in August 2012 caused it prejudice, when both sets of contentions were filed after the Markman decision. Plaintiffs' supplementation raises no new claim construction issues. No new claims are being asserted, and thus no new claim terms need be construed. *See Arbitron, Inc. v. Int'l Demographics Inc.*, No. 2:06-CV-434 (TJW), 2009 U.S. Dist. LEXIS 3191, at *7 (E.D. Tex. Jan. 16, 2009) (where amending contentions after claim construction order had issued resulted in no prejudice because "[t]he amendment has no impact on claim construction issues that the Court has already addressed.").

Finally, Plaintiffs provided Defendants with the Supplemental Contentions in a timely fashion, such that Defendants will have had over seven months to prepare a response in their expert reports. *See Avago Techs. Gen. IP Pte. Ltd., v. Elan Microelectronics Corp.*, No. 04-05385 JW (HRL), 2007 WL 1449758, at *2 (N.D.Cal. May 15, 2007) (finding no prejudice to amending contentions when the opposing party was on notice of the amended theory for almost three months before having to respond.). Thus Defendants will suffer no prejudice from Plaintiffs' Supplemental Contentions.

D. Public Policy Favors Amendment

In addition, public policy favors deciding patent issues on their merits, weighing strongly in favor of granting leave to amend. *See Avago Techs.*, 2007 WL 1449758, at *2 ("[T]he court wishes to have this invalidity issue decided on its merits, in the interest of promoting substance over form."). There is a long-standing judicial preference for cases to be decided on the merits, rather than on procedural grounds. *See Hill v. Williamsport Police Dept.*, No. 01-4530, 2003 WL 21466902, at *2 (3d Cir. Apr. 16, 2003) (stating a preference for "adjudications on the merits".) Indeed, courts are "extremely reluctant to dispose of substantive infringement claims

⁴ Notably, the Local Patent Rules recognize that good cause for amending contentions may arise after the issuance of a Markman ruling. *See* L. Pat. R. 3.7(a).

The Honorable Joel Schneider

February 1, 2013

Page 7

based upon procedural defects.” *Biogenex Labs., Inc. v. Ventana Med. Sys., Inc.*, No. 05-860 JF (PVT), 2006 WL 2228940, at *4 (N.D.Cal. Aug. 3, 2006.) Accordingly, Plaintiffs should be permitted the full opportunity to present all of the factual evidence concerning their infringement and validity theories, which Defendants have known about throughout this litigation.

In sum, L. Pat. R. 3.7 “is not a straitjacket into which litigants are locked from the moment their contentions are served” *TFH Publ’ns.*, 705 F. Supp. 2d at 366. Plaintiffs have shown that leave to amend is warranted here, based on newly-discovered information and case developments, about which Lupin and Mylan have been on ample notice. Accordingly, Plaintiffs respectfully request this Court grant them leave to amend their Infringement and Invalidity Contentions pursuant to L. Pat. R. 3.7.

Respectfully submitted,

/s/ *Karen Jacobs Loudon*

Karen Jacobs Loudon (#2881)

cc: All Counsel of Record

6981595